



Louisiana

Synthetic Cartilage Implants for Joint Pain

Policy # 00149

Original Effective Date: 06/01/2018

Current Effective Date: 06/01/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions is addressed separately in medical policy 00006.

Note: Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions is addressed separately in medical policy 00091.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers synthetic cartilage implants for the treatment of articular cartilage damage to be **investigational**.*

Background/Overview

ARTICULAR CARTILAGE DAMAGE

Articular cartilage damage may present as focal lesions or as more diffuse osteoarthritis (OA). Cartilage is a biological hydrogel that is comprised mostly of water with collagen and glycosaminoglycans and does not typically heal on its own. OA or focal articular cartilage lesions can be associated with substantial pain, loss of function, and disability. OA is most frequently observed in the knees, hips, interphalangeal joints, first carpometacarpal joints, first metatarsophalangeal (MTP) joint, and apophyseal (facet) joints of the lower cervical and lower lumbar spine. OA less commonly affects the elbow, wrist, shoulder, and ankle. Knee OA is the most common cause of lower-limb disability in adults over age 50. OA of the MTP joint with loss of motion (hallux rigidus) can also be severely disabling due to pain in the "toe-off" position of gait. An epidemiologic study found that OA of the first MTP joint may be present in as many as 1 in 40 people over the age of 50.

Treatment

Conventional treatment options for painful focal damaged articular cartilage of the knee include débridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Débridement involves the removal of the synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral abrasion techniques attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Diffuse OA of the knee, hip, or ankle may be treated with joint replacement.

Early-stage OA of the first MTP is typically treated with conservative management, including pain medication and change in footwear. Failure of conservative management in patients with advanced OA of the MTP joint may be treated surgically. Cheliectomy (removal of bone osteophytes) and interpositional spacers with autograft or allograft have been used as temporary measures to relieve pain.

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Although partial or total joint replacement have been explored for MTP OA, complications from bone loss, loosening, wear debris, implant fragmentation, and transfer metatarsalgia are not uncommon. Also, since the conversion of a failed joint replacement to arthrodesis has greater complications and worse functional results than a primary arthrodesis (joint fusion), MTP arthrodesis is considered the most reliable and primary surgical option. Arthrodesis can lead to a pain-free foot, but the loss of mobility in the MTP joint alters gait, may restrict participation in running and other sports, and limits footwear options, leading to patient dissatisfaction. Transfer of stress and arthritis in an adjacent joint may also develop over time.

Because of the limitations of MTP arthrodesis, alternative treatments that preserve joint motion are being explored. Synthetic cartilage implants have been investigated as a means to reduce pain and improve function in patients with hallux rigidus. Some materials such as silastic were found to fragment with use. Other causes of poor performance are the same as those observed with metal and ceramic joint replacement materials and include dislocation, particle wear, osteolysis, and loosening.

Synthetic polyvinyl alcohol (PVA) hydrogels have water content, and biomechanical properties similar to cartilage and they are biocompatible. PVA hydrogels have been used in a variety of medical products including soft contact lens, artificial tears, hydrophilic nerve guides, and tissue adhesion barriers. This material is being evaluated for cartilage replacement due to the rubber elastic properties and, depending on the manufacturing process, high tensile strength and compressibility.

The Cartiva implant is an 8- to 10-mm PVA disc that is implanted with a slight (1- to 1.5-mm) protrusion to act as a spacer for the first MTP joint. It comes with dedicated reusable instrumentation, which includes a drill bit, introducer, and placer. The Cartiva PVA implant was approved by the U.S. Food and Drug Administration (FDA) in 2016 for the treatment of arthritis of the MTP joint. It has been distributed commercially since 2002 with approval in Europe, Canada, and Brazil.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In July 2016, Cartiva[®] Synthetic Cartilage Implant (Cartiva, Alpharetta, GA) was approved by the FDA through the premarket approval process (P150017) for painful degenerative or posttraumatic arthritis in the first MTP joint along with hallux valgus or hallux limitus and hallux rigidus. Lesions greater than 10 mm in size and insufficient quality or quantity of bone are contraindications. Continued approval depends on a study evaluating long-term safety and effectiveness. The post-approval study will follow the subjects treated with Cartiva Synthetic Cartilage Implant for 5 years. FDA product code: PNW.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

EARLY-STAGE FIRST METATARSOPHALANGEAL OSTEOARTHRITIS

No studies were identified on use of synthetic cartilage implants for early-stage first MTP OA.

Section Summary: Early-Stage First Metatarsophalangeal Osteoarthritis

The evidence is insufficient to determine the effects of the synthetic cartilage implant for early-stage first MTP OA. RCTs and long-term follow-up are needed to determine implant survival and its effect on health outcomes.

ADVANCED FIRST MTP OA

FDA approval of the Cartiva synthetic cartilage implant was based on an unmasked multicenter noninferiority trial (MOTION) that compared the implant with arthrodesis of the first MTP joint. This trial, published by Baumhauer et al in 2016, included 197 patients with advanced hallux rigidus (Coughlin grade 2, 3, or 4 with a visual analog scale [VAS] score for pain $\geq 40/100$) who were randomized in a 2:1 ratio to the cartilage implant (n=132) or arthrodesis (n=65). Patients were excluded from the trial if they had lesions greater than 10 mm in size, hallux varus to any degree, or hallux valgus greater than 20°. Withdrawals after randomization were higher in the control group (15/65 vs 2/132), suggesting possible bias in expectations in favor of the novel joint preserving procedure. A modified intention-to-treat analysis was requested by the FDA to adjust for the difference in study withdrawals. The modified intention-to-treat analysis included 130 patients in the Cartiva group and 50 patients in the fusion group. The safety cohort included the randomized patients plus 22 nonrandomized run-in patients who received an implant.

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The primary outcome was a composite of a 30% or greater difference in VAS scores for pain, maintenance of function on the Foot and Ankle Ability Measure (FAAM) activities of daily living (ADL) subscale, and absence of major safety events at 2 years. The FAAM is a validated measure as sports activities and ADLs, with a minimal clinically important difference defined as 9 points for sports and 8 points for ADL subscales. The primary effectiveness endpoint was achieved by 80% of patients in both groups, and the implant met the 15% noninferiority margin ($p < 0.0075$). VAS pain scores decreased significantly in both groups but were consistently lower in the arthrodesis group from 6 weeks through 2 years (see Table 1). Nearly all patients (97%) who underwent fusion had a 30% or greater relief in pain compared with 89% of patients who received the implant. Maintenance of function, as measured by the FAAM ADL subscale, was observed in 98.3% of patients who received the implant and in 97.6% of patients who underwent fusion. Secondary surgeries were performed in 17 (11.2%) implant patients, in whom 14 (9.2%) implants were removed and converted to arthrodesis. In the arthrodesis group, 6 (12%) patients had removal of screws or screws and plates. As expected, dorsiflexion was significantly better in the implant group (29°) than in the fusion group (15° ; $p < 0.001$). Radiographic measurements showed 4 (8%) occurrences of mal-union or non-union in the fusion group and no device displacement, fragmentation, or avascular necrosis with the implant. Some instances of radiolucency, bony reactions, and heterotopic ossification were observed, but these events did not correlate with individual patient success. These events might impact future success and will be important to monitor with extended follow-up. The FDA-regulated safety and efficacy study of the randomized and nonrandomized Cartiva group is continuing through 5 years.

Further analysis of data (2017) from the pivotal trial did not identify any factors (e.g., hallux rigidus grade, preoperative pain, duration of symptoms, body mass index) that affected the success of the procedure. Analysis also raised questions whether Coughlin grade (symptoms, radiographic measures, range of motion), is the most appropriate method to identify patients for the procedure, leading the trialists to recommend using only clinical signs and symptoms to guide treatment.

Table 1. Outcome Scores for Synthetic Cartilage Implant and Arthrodesis

Outcomes	Baseline	6 Weeks	3 Months	6 Months	1 Year	2 Years
VAS pain						
Implant	68 (13.9)	33.3 (24.7)	29.4 (23.2)	28.9 (27.75)	17.8 (23.0)	14.5 (22.1)
Arthrodesis	69.3 (14.3)	17.2 (17.6)	15.5 (13.1)	11.7 (18.3)	5.7 (8.5)	5.9 (12.1)
p value	0.571	<0.001	<0.001	<0.001	0.001	0.002
FAAM ADL						
Implant	59.4 (16.9)	69.0 (19.0)	77.3 (17.70)	82.7 (17.5)	88.6 (14.4)	90.4 (15.0)
Arthrodesis	56.0 (16.8)	59.6 (24.8)	82.5 (14.9)	89.9 (12.4)	94.1 (6.8)	94.6 (7.1)
p value	0.222	0.008	0.079	0.014	0.018	0.082
FAAM sports						
Implant	36.9 (20.9)	39.5 (26.3)	55.1 (26.5)	66.6 (26.3)	75.8 (24.8)	79.5 (24.6)
Arthrodesis	35.6 (20.5)	22.4 (22.5)	53.9 (29.5)	78.6 (23.8)	84.1 (16.9)	82.7 (20.5)
p value	0.694	<0.001	0.804	0.010	0.043	0.461

Values are mean (standard deviation).

ADL: activities of daily living; FAAM: Foot and Ankle Ability Measure; VAS: visual analog score.

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Five-year follow-up was reported by Daniels et al (2017) for 27 patients from the pivotal trial who received the implant at 1 of 3 Canadian centers. Two additional patients were lost to follow-up, and 1 patient had persistent pain and converted to fusion, resulting in 96% implant survivorship. For the remaining patients, there were no radiographic changes in implant position, loosening, subsidence, or wear. Eight patients developed osteophytes, but none required surgery by the average 5.4-year follow-up (range, 4.9 to 6.4 years). VAS pain (5.7), and FAAM ADL subscale (95.3), and FAAM sports subscale (89.4) scores remained high ($p < 0.001$ vs baseline). It is expected that all patients from the original cohort will have 5- to 10-year follow-up by 2021.

Section Summary: Advanced First MTP OA

The evidence on synthetic cartilage implants in patients with advanced first MTP OA includes an RCT that compared a PVA hydrogel implant with arthrodesis. Results at 2 years from the pivotal trial showed pain scores that were slightly worse compared to patients treated with arthrodesis and similar outcomes between the groups for ADL and sports. Some bias in favor of the novel motion preserving implant is possible, as suggested by the high dropout rate in the arthrodesis group after randomization. Five-year follow-up was reported in 2017 for about 20% of the original cohort, and showed no evidence of degradation in the implant or outcome scores at this time. Follow-up of the complete cohort is continuing and will provide needed information on implant durability at 5 to 10 years. Corroboration of long-term results in an independent study would provide greater confidence in the effect of the implant on health outcomes.

ARTICULAR CARTILAGE LESIONS OF JOINTS OTHER THAN THE GREAT TOE

Use of PVA hydrogel implants has been reported in a few observational studies for articular cartilage lesions of the knee. A study is in progress to evaluate the PVA hydrogel implant for the OA of the first carpometacarpal joint, but the study is not expected to be completed until 2024. No other RCTs on synthetic cartilage implants for joints other than the great toe have been identified.

Section Summary: Articular Cartilage Lesions of Joints Other Than the Great Toe

The evidence is insufficient to determine the effects of the synthetic cartilage implant for joints other than the great toe. RCTs and long-term follow-up are needed to determine implant survival and the effect on health outcomes.

SUMMARY OF EVIDENCE

For individuals who have early-stage first MTP OA who receive a synthetic cartilage implant, the evidence is lacking. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal study was performed in patients with Coughlin stage 2, 3, or 4 hallux rigidus. No evidence was identified in patients with stage 0 to early-stage 2 hallux rigidus. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have advanced first MTP OA who receive a synthetic cartilage implant, the evidence includes a pivotal RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Arthrodesis is the established treatment for advanced arthritis of the great toe, although the lack of mobility can negatively impact sports and choice of footwear, and is not a preferred

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option of patients. Implants have the potential to reduce pain and maintain mobility in the first MTP joint but have in the past been compromised by fragmentation, dislocation, particle wear, osteolysis, and loosening. A PVA hydrogel implant has shown properties similar to articular cartilage in vitro and was approved by the FDA in 2016 for the treatment of painful degenerative or posttraumatic arthritis in the MTP joint. The pivotal trial compared the implant with arthrodesis and showed patient-reported pain scores to be slightly worse than arthrodesis with similar outcomes between the 2 groups on scores for ADL and sports. Five-year follow-up was reported in 2017 for about 20% of the original cohort, which showed no evidence of implant degradation or reduction in pain and function. Continued FDA approval depends on a 5-year follow-up of the complete cohort and will provide needed information on implant durability. There is a high possibility of bias in favor of the novel device. Corroboration of long-term results in an independent study would provide greater confidence in the findings of the pivotal trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have articular cartilage damage in joints other than the great toe who receive a synthetic cartilage implant, the evidence includes observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. No RCTs were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

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03/01/2018 Medical Policy Committee review

03/21/2018 Medical Policy Implementation Committee approval. New policy.

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Next Scheduled Review Date: 03/2019

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Code Type	Code
CPT	28291
HCPCS	L8699
ICD-10 Diagnosis	All related diagnoses

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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